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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,572	10/11/2005	Gerhard Hoefle	930008-2197	5809

7590 07/02/2008

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
07/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,572	HOEFLE ET AL.	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 3/4/2005 is acknowledged and has been entered.

Claims 1-34 are currently pending and are addressed herein.

Applicants response filed 2/4/08 is acknowledged and has been entered. The Application now appears to comply with the sequence rules.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 7, 9, drawn to (i) a ssDNA molecule having a sequence according to Figure 1; and, (ii) a ssDNA molecule that is at least 90% homologous to (i), but which differs by at least one nucleotide, and variants or mutants thereof, and a vector having the DNA sequence.

Group 2, claim(s) 1, 7, 9 drawn to a ssDNA molecule that is homologous to the molecule of Group I, and variants or mutants thereof, and a vector having the DNA sequence.

Group 3, claim(s) 2, 33, drawn to a dsDNA molecule comprising the ssDNA of claim 1 and a strand complementary thereto as well as variants or mutants thereof.

Groups 4-29, claim(s) 3, parts (i)-(xxvi), respectively; drawn to a ssDNA molecule according to parts (i)-(xxvi) of claim 3, respectively. That is, each of parts (i)-(xxvi) of claim 3 is a different group and should Applicants wish to elect one of the parts of claim 3, Applicants should clearly identify the specific part of claim 3 they elect (i.e., Applicants should identify one of parts (i)-(xxvi) for election). Further, should Applicants elect any of parts (xxiv)-(xxvi) (i.e., Groups 27-29), Applicants are further required to identify one specific molecule (i.e., one specific molecule of (i)-(xxiii)) to which the ssDNA is hybridisable, homologous or complementary.

Group 30, claim(s) 4, drawn to a dsDNA molecule comprising a ssDNA molecule of claim 3 and a strand complementary thereto. Should Applicants elect Group 30, Applicants are further

required to identify the specific ssDNA molecule of claim 3 (i.e., one of (i)-(xxvi)) which is the ssDNA of the elected dsDNA molecule.

Groups 31-63, claim(s) 5, parts (i)-(xxxiii), respectively; drawn to a ssDNA molecule selected from one of parts (i)-(xxxiii), respectively. That is, each of parts (i)-(xxxiii) of claim 5 is a different group and should Applicants wish to elect one of the parts of claim 5, Applicants should clearly identify the specific part of claim 5 they elect (i.e., Applicants should identify one of parts (i)-(xxxiii) for election). Further, should Applicants elect any parts (xxxi)-(xxxiii) (i.e., Groups 62-64), Applicants are further required to identify one specific molecule (i.e., one specific molecule according to (i)-(xxx)) to which the ssDNA is hybridisable, homologous or complementary.

Group 64, claim(s) 6, drawn to a dsDNA molecule comprising a ssDNA molecule of claim 5 and a strand complementary thereto. Should Applicants elect Group 60, Applicants are further required to identify the specific ssDNA molecule of claim 5 (i.e., one of (i)-(xxxiii)) which is the ssDNA of the elected dsDNA molecule.

Group 65, claim(s) 8, 10, 11 drawn to an RNA corresponding to a sequence according to claim 1 and the cell of claims 10, 11. Should Applicants this Group, they are further required to identify which ssDNA the RNA molecule corresponds to (i.e., parts (i), (ii) or (iii) of claim 1).

Group 66, claim(s) 12, 13, drawn to use of the sequence of claim 8.

Group 67, claim(s) 14, drawn to an expression product of a DNA molecule of claim 1. Should Applicants this Group, they are further required to identify which ssDNA molecule of claim 1 (i.e., parts (i), (ii) or (iii) of claim 1) from which the expression product is derived.

Group 68, claim(s) 15-18, 24, 25, 29, 34 drawn to a polynucleotide comprising SEQ ID NO: 1 or fragment thereof, a vector comprising the polynucleotide, a cell comprising the vector, a pharmaceutical composition comprising the polynucleotide, and a kit comprising the polynucleotide.

Group 69, claim(s) 15-18, 24, 25, 29, 34 drawn to a polynucleotide comprising SEQ ID NO: 18 or fragment thereof, a vector comprising the polynucleotide, a cell comprising the vector, a pharmaceutical composition comprising the polynucleotide, and a kit.

Group 70, claim(s) 15-18, 24, 25, 29, 34 drawn to a polynucleotide comprising SEQ ID NO: 33 or fragment thereof, a vector comprising the polynucleotide, a cell comprising the vector, and a pharmaceutical composition comprising the polynucleotide and a kit.

Group 71, claim(s) 15-18, 24, 25, 29, 34 drawn to a polynucleotide comprising SEQ ID NO: 36 or fragment thereof, a vector comprising the polynucleotide, a cell comprising the vector, and a pharmaceutical composition comprising the polynucleotide and a kit.

Groups 72-106, claim(s) 19, 24 and 25 drawn to the polypeptide defined in SEQ ID NO: 2-17, 19-32, 34, 35, 37 and 38 (including fragments/derivatives thereof), respectively as well as a pharmaceutical composition comprising the polynucleotide. Should Applicants wish to elect one of these Groups, Applicants must identify the specific SEQ ID NO they wish to elect.

Groups 107-145, claim(s) 21-23, drawn to use of the polynucleotide of SEQ ID NO: 1, 18, 33, or 36 or the polypeptide of SEQ ID NO: 2-17, 19-32, 34, 35, 37, 38 (and fragments/variants thereof), respectively. Should Applicants wish to elect one of these Groups, Applicants must identify the specific SEQ ID NO they wish to elect.

Groups 146-184, claim(s) 26 and 27, drawn to a method of producing protein comprising expressing any one of SEQ ID NOS: 1, 18, 33, 36, 2-17, 19-32, 34, 35, 37, 38 (and fragments thereof) and purifying the expression product. Should Applicants wish to elect one of these Groups, Applicants must identify the specific SEQ ID NO they wish to elect.

Group 185-189, claim(s) 28, drawn to a method of identifying genes which are involved in the biosynthesis of tubulysins comprising the steps of hybridization of SEQ ID NO: 1, 18, 33, 36 (and fragments thereof) with nucleic acid of a species that is not Angiococcus disciformus and isolating and characterizing the hybridized nucleic acid. Should Applicants wish to elect one of these Groups, Applicants must identify the specific SEQ ID NO they wish to elect.

Groups 190-224, claim(s) 30-32, drawn to use of the polypeptide of SEQ ID NO: 2-17, 19-32, 34, 35, 37, 38 (and biologically active fragments/derivatives thereof) as a disinfectant. Should Applicants wish to elect one of these Groups, Applicants must identify the specific SEQ ID NO they wish to elect.

The inventions listed as Groups 1-224 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: there is a lack of unity since the broadest claim does not provide a special technical feature over the prior art. PCT Rule 13.2 states "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes ***over the prior art***. (emphasis added)" In the instant case, claim 1 encompasses a ssDNA molecule *having a according to Figure 1, or a ssDNA sequence that is at least 90% identical to that ssDNA molecule*. It is noted that there is no particular size limit to the ssDNA molecule, as such, the claim encompasses any sequence, regardless of size that comprises any sequence within Figure 1, including sequences which are at least 90% identical to the sequence of Figure 1, regardless of size. U.S. Patent Application publication 2002/053519 teaches an array comprising all possible 10mers (e.g., see Example 2 beginning on page 12).Since the DNA sequence of claim 1 is anticipated, this claim provides no special technical feature over the prior art and the separation of the claims into the different groups is proper.

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The claims encompass the species of cells indicated in claim 11.

The claims encompass the species of pathogenic infections indicated in claim 23.

Applicant is required, in reply to this action, to elect a single species of cell and a single species of pathogenic infection to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species listed above in the following manner: Claim(s) 8, 10 and 11 are generic to the species of cells of claim 11. Claim(s) 21-23 are generic to the species of pathogenic infections of claim 23.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the indicated cells and pathogenic infections are not novel as they were well known, and thus there is no special technical feature linking the species.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635